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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/367,013	08/05/1999	DEBORAH KNUTZON	CGAB-210-USA	3773

28343            7590            12/31/2002

MONSANTO COMPANY / ABBOTT LABORATORIES  
C/O MCCUTCEN, DOYLE, BROWN & ENERSEN LLP  
THREE EBARCADERO  
SUITE 1800  
SAN FRANCISCO, CA 94111-4067

EXAMINER

NASHED, NASHAAT T

ART UNIT

PAPER NUMBER

1652

DATE MAILED: 12/31/2002

24

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No. <b>09/367,013</b>	Applicant(s) <b>Knutzon et al.</b>
Examiner <b>Nashaat T. Nashed</b>	Art Unit <b>1652</b>

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

1)  Responsive to communication(s) filed on Nov 4, 2002

2a)  This action is FINAL.      2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

### Disposition of Claims

4)  Claim(s) 189-196, 199-208, 210-244, and 255-296 is/are pending in the application.

4a) Of the above, claim(s) 189-196, 199-208, 210-214, 285-291, 293, 294, e is/are withdrawn from consideration.

5)  Claim(s) \_\_\_\_\_ is/are allowed.

6)  Claim(s) 215-244, 255-284, 292, and 295 is/are rejected.

7)  Claim(s) \_\_\_\_\_ is/are objected to.

8)  Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on \_\_\_\_\_ is/are a)  accepted or b)  objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)  The proposed drawing correction filed on \_\_\_\_\_ is: a)  approved b)  disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)  The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

13)  Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)  All b)  Some\* c)  None of:

1.  Certified copies of the priority documents have been received.
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

14)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a)  The translation of the foreign language provisional application has been received.

15)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

1)  Notice of References Cited (PTO-892)

4)  Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_

2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)

5)  Notice of Informal Patent Application (PTO-152)

3)  Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_

6)  Other: \_\_\_\_\_

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 4, 2002 has been entered.

The application has been amended as requested in the communication filed November 4, 2002. Accordingly, claims 197, 198, 209, and 245-254 have been canceled, claims 189, 201, 205, 208, 214, 215, 225, 235, 255, 265, and 275, and new claims 285-296 have been entered. Amended claim 245 has not been entered because claim 245 has been canceled in the same amendment.

Claims 189-214 remain withdrawn from further consideration. The claims in this application has been previously restricted in paper number 12, and applicant made an election without traverse of both the elected method and the species. Applicant still arguing that this application claim priority from an application in which SEQ ID NO: 1 was found patentable, and thus, SEQ ID NO: 1 is the contribution of the applicants. Applicants argument have been fully considered, but they are found unpersuasive. The inventive entities of this application and the parent application serial number 08/834,655, U. S. P. 5,968,809 ('809) are different. The '809 patent has only one inventor, Deborah Kuntzon, whereas the instant application has six inventor including Deborah Kuntzon. Since the inventive entity in the parent and the instant application are different, the nucleic acid sequence of SEQ ID NO: 1 was invented by others at the time the PCT application was filed. Thus, as indicated in the prior Office action, paper number 20, the restriction between claims 189-214 and those of elected claims 215-284 is proper. New claims 285-291, 293, 294 and 296 are drawn to either a method of making cell culture (claims 291 and 294) which is the same subject matter of non-elected claims 189-214 and the product of a method, i. e., cell culture (claims 285-290, 293, and 296). Since the cell culture can't be made by any other method, claims drawn to the cell culture are included with the non-elected subject matter of method of making a cell cultur of claims 189-214, 291 and 294 as a single Group, and therefore, they are withdrawn from further consideration. The restriction is made **FINAL**.

Claims 215-244, 255-284, 292 and 295 are under consideration.

Claims 215-244, 255-284, 292, and 295 are objected to because they are dependent on non-elected subject matter. For examination purposes only, all the embodiment of the parent claims are included in the examined claims. Appropriate correction is required.

The terminal disclaimer filed on October 31, 2002 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of U.

S. Patents 6,136,574; 6,075,183; and 5,968,809 has been reviewed and is accepted. The terminal disclaimer has been recorded.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 225-244 and 265-284 rejected under 35 U.S.C. § 112, first paragraph, as the disclosure is enabling only for claims limited to methods of a lipid fraction enriched in stearidonic acid using yeast transformed with the nucleic acid sequences encoding Δ-6-desaturase of SEQ ID NO: 2 including SEQ ID NO: 1 from *Mortierella alpina* for the reasons set forth in the prior Office action, paper number 20.

Applicants argue that identification of whether or not a protein or nucleic acid has a homology to a disclosed sequence and a deletion analysis of a given gene is routine experimentation in the art and that the specification provides extensive teachings regarding deletions, insertions and methods of mutating isolated sequences.

Applicants' arguments filed 11/4/02 have been fully considered but they are not deemed to be persuasive. Enablement requires a disclosure sufficient to allow a person of skill in the art to practice the full scope of the claimed invention without undue experimentation. The previous Office action sets out a *prima facie* case of non-enablement, explaining by sound scientific reasoning why a person of ordinary skill in the art would doubt that the guidance of the specification would enable practice of the full scope of the claimed invention without undue experimentation. Applicants have presented no evidence or, indeed, any arguments to establish the adequacy of the disclosure to enable the scope of the instant claims. Applicants merely assert that the disclosure of the nucleic acid sequences and the teaching of the specification is sufficient enablement for the claims. The Examiner is in full agreement with the applicants that, given a nucleic/amino acid sequence, one of ordinary skill in the art can identify the sequence homology with SEQ ID NO: 1 or 2 and that mutation methods of couple of residues are taught in the specification and are well known in the prior art, but these are not the enablement issues in the prior Office action, paper number 20. The major issues are identifying a nucleic/amino acid sequence having 60% or 80% sequence homologies to SEQ ID NO's: 1 and 2 which may require redesigning 40% or 20% of the amino acid sequence while maintaining catalytic activity. The specification does not provide any teaching of any methods or any example showing redesigning of 20% of the amino acid

sequence of SEQ ID NO: 2 is possible. Redesigning 20% of amino acid residues of proteins is not known in the prior art and one of ordinary skill in the art would not be able carry out the claimed invention. Applicants make no effort to explain why they consider the disclosure of the nucleic acid sequence of SEQ ID NO: 1 and the amino acid sequence of SEQ ID NO: 2 is sufficient to enable the claims of nucleic and amino acid sequence having 80% sequence homologies to the disclosed sequences. Conclusory statements unsupported by evidence or scientific reasoning are insufficient to overcome the *prima facie* case of non-enablement set out in the previous Office action. As for the allowed claims in serial number 09/377,452 involving  $\Delta$ 5-desaturase from *M. alpina* are irrelevant to the prosecution of the pending claims in serial number 09/367,013. Thus, the claims remain rejected.

Claims 215-244, 255-284, 292 and 295 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following are the reasons for the rejections:

- (a) the methods of claim 215, 225, 235, 255, 265, and 275 are incomplete because they are omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: (a) culturing a host microbial cell transformed with a nucleic acid comprising the nucleic acid sequence encoding the desaturase of SEQ ID NO: 2; (b) inducing the cell to produce the desaturase of SEQ ID NO: 2 in sufficient quantity to produce stearidonic acid; and (c) isolating the oil containing the stearidonic acid from the cell culture.
- (b) the phrases "hybridizes to the complement of the sequence depicted in SEQ ID NO: 1" and (new rejection) "under hybridization conditions suitable for sequencing said complement" in claim 275 render the claim indefinite and confusing, respectively, because the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Since nucleic acid are no to hybridize to any other nucleic acid sequence under different conditions, the nucleic acid sequence of SEQ ID NO: 1 is expected to hybridize to any nucleic acid sequence. Thus, the claim is considered indefinite. Since the specification does not contain any specific hybridization conditions, the claim can't be amended to obviate this rejection. The new phrase "under hybridization conditions suitable for sequencing said complement" is not defined or found in the specification and one of ordinary skill in the art would not know its meaning. The phrase constitute a new matter and should be deleted.
- (c) (new rejection) the phrase "substantially identical" in claims 292 and 295 renders the claims indefinite because the resulting claim does not clearly set forth the metes and bounds of the patent protection desired.

- (d) Claims 225-234, 236-244, 246-254, 256-264, 266-274, and 276-284 are included in this rejection and do not cure the deficiencies of the claims from which they depend.

In response to the above rejections, Applicants traverse the rejections on the ground that (a) is dependent from other claims which should provide the needed missing steps, and (b) the claim is clear.

Applicants' arguments filed 11/4/02 have been fully considered but they are not deemed to be persuasive. (a) The claims remain dependent on non-elected subject matter without traverse and the non-elected claims are withdrawn from further consideration. Thus, the claims as written are incomplete and need additional steps as indicated in the previous Office action, paper number 20. (b) Claim 275 is perfectly clear, but one of ordinary skill in the art would recognize clearly its indefiniteness. The claim has no bases in the specification as amended, and should be deleted.

Claims 215-224 and 255-264 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nashaat T. Nashed, Ph. D. whose telephone number is (703) 305-6586. The examiner can normally be reached Monday, Tuesday, Thursday and Friday from 9:00 a.m. to 5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached on (703) 308-3804. The fax phone number for this Group is (703) 305-7401.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.



Nashaat T. Nashed, Ph. D.  
Primary Examiner